

AMENDMENTS TO THE SPECIFICATION:

Please replace the paragraph that begins on page 2, line 28, of the specification, as filed with the following replacement paragraph:

In accordance with various aspects of the present invention, a sheath having a sheath layer removably covers a device such as a balloon of a catheter assembly. The balloon is capable of carrying a therapeutic substance, for example, via an implantable device or prosthesis, one example of which includes a stent. In one embodiment, the sheath layer is formed from a barrier material that prevents the therapeutic substance from significantly diffusing from the device and ~~absorbed~~ absorbing into the sheath layer. In another embodiment, a barrier layer formed from the barrier material can be disposed on the inside surface of the sheath layer.

Please replace the paragraph that begins on page 5, line 3, of the specification, as filed with the following replacement paragraph:

In accordance with another embodiment, sheath layer and balloon wall can be made from a polymeric material having a main group element oxide layer, such as silicone oxide, or metal oxide layer formed on the therapeutic substance contacting surface of sheath layer and balloon wall.

Please replace the paragraph that begins on page 6, line 15, of the specification, as filed with the following replacement paragraph:

“Polymer,” “poly,” and “polymeric” ~~means~~ mean the product of a polymerization reaction and ~~is~~ are inclusive of homopolymers, copolymers, terpolymers etc., including random, alternating, block, and graft variations thereof[[:]].

Please replace the paragraph that begins on page 6, line 27, of the specification, as filed with the following replacement paragraph:

Referring now to the drawings, wherein similar parts are identified by like reference numerals, Figure 1 is a partial view of a catheter assembly 10, that is well known by one of ordinary skill ~~and~~ in the art and used in a variety of medical procedures such as percutaneous transluminal coronary angioplasty (PTCA), vascular prosthetic implantation, and atherectomy. The type of catheter assembly 10 is not of critical importance. Catheter assembly 10 includes catheter tube 12 having a guidewire lumen 14. Guidewire lumen 14 is configured to receive a guidewire (not shown) which is used to maneuver catheter tube 12 through the vasculature of a subject.

Please replace the paragraph that begins on page 8, line 18, of the specification, as filed with the following replacement paragraph:

In an alternative embodiment, as illustrated in Figures 2B and 3B, a barrier layer 38 formed from the barrier material may be formed on the inside surface of sheath layer 24, such as the therapeutic substance-contacting surface, or on the outside surface of balloon wall 20, such as the therapeutic substance-contacting surface. The underlying sheath layer 24 and balloon wall 20 can be made from any suitable material. For sheath 22, barrier layer 38 has any suitable thickness. For balloon 16, the total thickness T_{B2} of balloon wall 20 and barrier layer 38 is any thickness that does not compromise desirable properties of the balloon. As indicated above, total thickness T_{B2} should not hinder optimum performance characteristics including high burst strength, low compliance, good flexibility, high resistance to fatigue, folding ability, the ability to cross and recross the desired site of treatment, and low susceptibility to defect caused by handling. By way of example, and not limitation, barrier layer 38 can have a thickness of about 0.1 to about 25 microns with the underlying balloon wall 20 having a thickness of about 5 to 75 microns. A specific choice of thickness T_{B2} depends on the anatomy and size of the target vessel in which balloon 16 is inserted. The structures of Figure 2B and 3B can be manufactured, for example, by lamination, co-extrusion, or coating. Lamination is the

process of adhesively bonding two or more materials. Co-extrusion is the process of extruding two or more materials through a single die with two or more orifices arranged so that the extrudants merge and weld together into a laminar structure. The laminar structure, for example is then chilled such as by quenching. Coating is a process in which a liquid is applied continuously to a moving sheet to produce a uniform application of the fluid onto and/or within the sheet. The processes of lamination, co-extrusion, and coating are well known to one of ordinary skill in the art.